REMARKS

After entry of the instant amendment, claims 49 to 86 and 133 to 145 will remain pending. Claims 115 to 132 are cancelled herein, without prejudice to pursuit of same in one or more divisional applications. No claims have been amended.

The Office Action dated January 24, 2006 included a restriction requirement under 35 U.S.C. § 121. Applicants now affirm the provisional election made in the telephone interview with the Examiner of the invention of Group I, which encompasses claims 49 to 86 and 133 to 145. Claims 115 to 132, which were directed to the invention of Group II, have been cancelled.

Applicants also confirm the provisional election of species, wherein the dosage unit is in the form of a tablet, and the condition to be treated is selected from the group consisting of narcolepsy, idiopathic hypersomnia, sleep apnea, and obstructive sleep apnea. It is Applicants' understanding that this species election is being made to aid the Examiner in conducting a search and examination of the claimed subject matter, and is not to be construed as limiting the scope of Applicants' claims. It is also Applicants' understanding that if the elected subject matter is found to be allowable over the prior art, the search and examination will be expanded to cover other species, until it includes the full scope of the generic claims included in the elected group. Applicants note that all of the pending claims read on the elected species.

The pending claims stand rejected under 35 U.S.C. § 103 as obvious over Grebow et al., U.S. Patent No. 5,618,845 ("Grebow"). Applicants respectfully traverse this rejection.

The present invention is directed to modafinil-containing pharmaceutical dosage units and methods of treatment utilizing same. Independent claim 49 specifies that more than about 5% of the total cumulative modafinil particles are more than about 200 microns in diameter, and that at least about 10% of the total cumulative modafinil particles are less than about 25 microns in diameter. Independent claim 134 specifies that more than 5% of the modafinil particles have diameters greater than 220 microns. The independent claims further specify that the dosage units are *bioequivalent* to a dosage unit in which at least about 95% of the particles have diameters less than about 200 microns.

Grebow, in contrast, describes and claims compositions wherein "not more than about 5% of the cumulative total (percent cumulative) of modafinil particles in any one dose provided to a mammal have particle sizes greater than about 200 microns." *See* col. 3, lines 16 to 20. Moreover, the patent teaches that "particle size, and the consistency of the particle size, of modafinil can have a significant effect on its potency and safety profile." *See* col. 4, lines 53 to 55. Indeed, the patent reports that changes in particle size distribution lead to different drug release rates, which in turn results in changes in pharmacokinetics that can lead to adverse side effects. *See e.g.*, col. 8, line 53 to col. 9, line 36. For example, Grebow teaches that "early" lots (*see e.g.* Fig 1, lots E-A through E-D) containing higher percentages (*i.e.*, > about 5%) of modafinil particles with diameters greater than 5% had lower potency than the "late" lots. *See* col. 4, line 53 to col. 5, line 21.

Thus, Grebow does not describe, and indeed *teaches away*, from compositions such as those instantly claimed, with contain higher percentages (greater than about 5%) of larger modafinil particles (greater than about 200 microns, or more), which are *bioequivalent* to compositions in which less than about 5% of the modafinil particles have diameters greater than about 200 microns. Indeed, there is no teaching or suggestion in Grebow that dosage forms such as those presently claimed in the instant application would be desirable, or of how to achieve such bioequivalent dosage forms.

In view of the foregoing, Applicants respectfully request that the rejection under 35 U.S.C. § 103 over Grebow be withdrawn. There being no other issues pending, a Notice of Allowance of all of pending claims 49 to 86 and 133 to 145 is respectfully requested.

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